Therapeutic Goods Legislation Amendment (2022 Measures No. 2) Regulations 2022

I, General the Honourable David Hurley AC DSC (Retd), Governor-General of the Commonwealth of Australia, acting with the advice of the Federal Executive Council, make the following regulations.

Dated 29 September 2022

David Hurley
Governor-General

By His Excellency's Command

Mark Butler
Minister for Health and Aged Care

Contents

1 Name

This instrument is the *Therapeutic Goods Legislation Amendment (2022 Measures No. 2) Regulations 2022*.

2 Commencement

(1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information

Column 1	Column 2	Column 3
Provisions	**Commencement**	**Date/Details**
1. Sections 1 to 4 and anything in this instrument not elsewhere covered by this table	1 July 2022.	1 July 2022
2. Schedule 1	1 July 2022.	1 July 2022
3. Schedules 2 and 3	The day after this instrument is registered.	1 October 2022

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

(2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3 Authority

This instrument is made under the *Therapeutic Goods Act 1989*.

4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1—Extension of transitional period for IVD companion diagnostics

Therapeutic Goods (Medical Devices) Regulations 2002

1 Subregulations 11.54(2) and (6)

Omit "1 July 2022", substitute "26 May 2026".

Schedule 2—Fee for application for consent of Secretary

Therapeutic Goods (Medical Devices) Regulations 2002

1 Division 9.1A (heading)

Omit "**patient implant cards and patient information leaflets**", substitute "**information requirements**".

2 Paragraph 9.1AA(1)(b)

Repeal the paragraph, substitute:

(b) the application is made solely in relation to:

(i) the application of either or both of clauses 13A.2 and 13A.3 of Schedule 1 to the medical device; or

(ii) the application of one or more of clauses 13.1 to 13.4 of Schedule 1 to the medical device, and the reason for the medical device not complying with one or more of those clauses is that the medical device is affected by the EU transition (within the meaning of subregulation (3)); or

(iii) both subparagraphs (i) and (ii);

3 Paragraph 9.1AA(2)(b)

Repeal the paragraph, substitute:

(b) the application is made solely in relation to:

(i) the application of either or both of clauses 13A.2 and 13A.3 of Schedule 1 to the medical devices; or

(ii) the application of one or more of clauses 13.1 to 13.4 of Schedule 1 to the medical devices, and the reason for the medical devices not complying with one or more of those clauses is that the medical devices are affected by the EU transition (within the meaning of subregulation (3)); or

(iii) both subparagraphs (i) and (ii);

4 At the end of regulation 9.1AA

Add:

(3) For the purposes of this regulation, a medical device is ***affected by the EU transition*** if:

(a) the medical device is of a kind included in the Register; and

(b) the basis of certifying the matter referred to in paragraph 41FD(f) of the Act for devices of that kind was an overseas regulator conformity assessment document issued under one of the following (as in force from time to time):

(i) Council Directive 90/385/EEC of the Council of the European Communities;

(ii) Council Directive 93/42/EEC of the Council of the European Communities;

(iii) Directive 98/79/EC of the European Parliament and the Council of the European Union; and

(c) a new overseas regulator conformity assessment document has been issued, or is expected to be issued, in respect of devices of that kind under one of the following (as in force from time to time):

(i) Regulation 2017/745 of the European Parliament and the Council of the European Union;

(ii) Regulation 2017/765 of the European Parliament and the Council of the European Union.

5 In the appropriate position in Part 11

Insert:

Division 11.15—Application provisions relating to the Therapeutic Goods Legislation Amendment (2022 Measures No. 2) Regulations 2022

11.68 Fee for application for consent of Secretary

(1) The amendments of Part 9 made by Schedule 2 to the *Therapeutic Goods Legislation Amendment (2022 Measures No. 2) Regulations 2022* apply in relation to an application for consent that is made on or after the commencement of those amendments.

(2) If:

(a) on or after 1 January 2022 and before the commencement of this regulation, a person made an application of a kind covered by paragraph (a) or (b) of item 1.15 of the table in Part 1 of Schedule 5; and

(b) the application was made in relation to the application of one or more of clauses 13.1 to 13.4 of Schedule 1 to the medical device or devices; and

(c) the reason for the medical device or devices not complying with one or more of those clauses was that the device or devices were affected by the EU transition (within the meaning of subregulation 9.1AA(3) of these Regulations); and

(d) the application was made:

(i) solely in relation to the application of one or more of those clauses; or

(ii) also in relation to the application of either or both of clauses 13A.2 and 13A.3 of Schedule 1, but not any other provision; and

(e) on or after 1 January 2022 and before the commencement of this regulation, the person paid the fee applicable in relation to the application under item 1.15 of the table in Part 1 of Schedule 5;

the Secretary must, on behalf of the Commonwealth, refund to the person the difference between the fee paid and the fee that would have been applicable in relation to the application under regulation 9.1AA if the application had been made on the day on which this regulation commences.

Schedule 3—Biological (priority applicant) determinations

Therapeutic Goods Regulations 1990

1 Section 2

Insert:

biologicals (priority applicant) determination has the meaning given by subsection 32DEA(2) of the Act.

2 After Part 3C

Insert:

Part 3D—Biologicals (priority applicant) determinations

16U Application of Part

For the purposes of subsection 32DEA(1) of the Act, this Part makes provision for and in relation to the making of biologicals (priority applicant) determinations.

16V Application for biologicals (priority applicant) determination

(1) A person may apply to the Secretary for a biologicals (priority applicant) determination in relation to a biological, other than a Class 1 biological.

(2) An application under subregulation (1) must:
  (a) be in writing; and
  (b) be in a form approved, in writing, by the Secretary; and
  (c) have with it written information in such detail as is reasonably necessary to allow the application to be properly considered.

(3) An application under subregulation (1) is taken to not have been made unless:
  (a) the application meets the requirements in subregulation (2); and
  (b) the fee prescribed in item 2A in Part 2 of Schedule 9A for making the application has been paid.

16W Making of biologicals (priority applicant) determination

(1) On receiving an application under subregulation 16V(1) for a biologicals (priority applicant) determination in relation to a biological, the Secretary must:
  (a) consider the application; and
  (b) decide either:
    (i) to make the determination; or
    (ii) to refuse to make the determination.

Criteria

(2) The Secretary may make the determination if the Secretary is satisfied, having regard to any matter that the Secretary considers relevant, that all of the following criteria are satisfied in relation to the biological:

(a) the biological is separate and distinct from biologicals included in the Register;

(b) either:

(i) for a Class 2 biological—an intended clinical use (the ***priority indication***) of the biological is the treatment, prevention or diagnosis of a life-threating or seriously debilitating condition; or

(ii) for a Class 3 or Class 4 biological—a therapeutic indication (the ***priority indication***) of the biological is the treatment, prevention or diagnosis of a life-threatening or seriously debilitating condition;

(c) either:

(i) no therapeutic goods that are intended to treat, prevent or diagnose the condition are included in the Register (except in the part of the Register for goods known as provisionally registered goods); or

(ii) if one or more therapeutic goods that are intended to treat, prevent or diagnose the condition are included in the Register (except in the part of the Register for goods known as provisionally registered goods)—there is substantial evidence demonstrating that the biological provides a significant improvement in the efficacy or safety of the treatment, prevention or diagnosis of the condition compared to those goods;

(d) there is substantial evidence demonstrating that the biological provides a major therapeutic advance.

Note: For paragraph (a), see section 32AB of the Act and regulation 11A for when a biological is separate and distinct from other biologicals.

Information to be specified in the determination

(3) The determination must specify:

(a) the person who, as a result of section 32DEA of the Act, is the priority applicant; and

(b) each active ingredient of the biological to which the determination relates; and

(c) the priority indication of the biological.

Notification of decision

(4) As soon as practicable after making the decision, the Secretary must notify the applicant, in writing, of the decision.

(5) If the Secretary decides to refuse to make the determination, the notification must include the reasons for the decision.

16X Period during which biologicals (priority applicant) determination is in force

(1) A biologicals (priority applicant) determination in relation to a biological:

(a) comes into force on the day on which the Secretary notifies the priority applicant in accordance with subregulation 16W(4); and

(b) subject to subregulation (2) and regulation 16Y, remains in force for 6 months.

(2) If the priority applicant specified in the determination makes an application under section 32DD of the Act to include the biological in the Register that passes preliminary assessment before the end of the 6 month period beginning when the determination comes into force, the determination remains in force until:

(a) the priority applicant withdraws the application; or

(b) the application lapses in accordance with section 32DH of the Act; or

(c) the application is finally determined.

Note: See subsection 32DDA(3) of the Act for when an application passes preliminary assessment.

16Y Revocation of biologicals (priority applicant) determination

(1) The Secretary may revoke a biologicals (priority applicant) determination in relation to a biological if:

(a) either:

(i) the priority applicant specified in the determination has not made an application under section 32DD of the Act to include the biological in the Register; or

(ii) the priority applicant has made such an application, but the application does not pass preliminary assessment; and

(b) the Secretary is satisfied that the criteria specified in subregulation 16W(2) are no longer satisfied in relation to the biological.

Note: See subsection 32DDA(3) of the Act for when an application passes preliminary assessment.

(2) The revocation must be by written notice given by the Secretary to the priority applicant.

3 Subregulation 48(1) (definition of *eligible person*, at the end of the cell at table item 2, column 1)

Add "or biologicals (priority applicant) determination".

4 Subregulation 48(1) (definition of *eligible person*, at the end of the cell at table item 3, column 1)

Add "or biologicals (priority applicant) determination".

5 Subregulation 48(1) (after paragraph (ed) of the definition of *initial decision*)

Insert:

(ee) subparagraph 16W(1)(b)(ii);

(ef) subregulation 16Y(1);

6 Part 2 of Schedule 9A (after table item 2)

Insert:

2A	Application fee for the purposes of paragraph 32DEA(3)(d) of the Act for a	$13,971

biologicals (priority applicant) determination in relation to a biological

7 Part 2 of Schedule 9A (table items 4 to 6)

Repeal the items, substitute:

4	Evaluation of a Class 2 biological for inclusion in the Register for subsection 32DI(1) of the Act:	
	(a) for a biological in relation to which a biologicals (priority applicant) determination is in place	$81,397 for each evaluation
	(b) in any other case	$77,873 for each evaluation
5	Evaluation of a Class 3 biological for inclusion in the Register for subsection 32DI(1) of the Act:	
	(a) for a biological in relation to which a biologicals (priority applicant) determination is in place	$163,197 for each evaluation
	(b) in any other case	$155,849 for each evaluation
6	Evaluation of a Class 4 biological for inclusion in the Register for subsection 32DI(1) of the Act:	
	(a) for a biological in relation to which a biologicals (priority applicant) determination is in place	$263,710 for each evaluation
	(b) in any other case	$253,217 for each evaluation